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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,450

12/05/2003

Christina Khoo

7129-00

1031

23909 7590 08/17/2009  
COLGATE-PALMOLIVE COMPANY  
909 RIVER ROAD  
PISCATAWAY, NJ 08855

EXAMINER

FORD, ALLISON M

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

08/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,450	<b>Applicant(s)</b> KHOO ET AL.	
	<b>Examiner</b> ALLISON M. FORD	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

Applicant's submission filed on 5/6/2009 has been entered. Claims 19 and 28 have been amended; claims 1-18 and 20-25 are cancelled; no new claims were added. Claims 19 and 26-28 are currently pending in the application, all of which have been considered on the merits.

### *Response to Arguments/Amendments*

Applicants' remarks filed 5/6/09 have been fully considered, and will each be addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicants have amended claim 19 to clarify that from about 30 ug to about 50 ug ascorbic acid is provided *per gram of pet food composition*. Applicants have also amended claim 28 to obviate the rejection thereof. However, the claims remain rejected as indefinite because it is unclear how the 30-50ug of ascorbic acid (recited in claim 19) correlates to the concentration of antioxidants provided in the pet food composition.

**Claims 19 and 26-28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

In claim 19 it remains unclear if the 30 to 50 ug ascorbic acid per gram of pet food composition is *in addition* to the 0.1% to 3% by weight antioxidants, or if the 30 to 50 ug ascorbic acid per gram of pet food composition is *part of* the 0.1% to 3% by weight antioxidants.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Applicant's arguments with respect to claims 19 and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

**Claims 19 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice*, 2002), in light of "Glutamine" The World's Healthiest Foods and Hamada et al (*Journal of Chromatography A*, 1998), and taken in view of Guilford (*Journal of Small Animal Practice*, 1994) and Hickman (*Clinical Techniques in Small Animal Practice*, 1998).**

Chandler discloses a recipe for a diet for treatment of gastrointestinal disorders in cats, comprising:

100 g rice cereal powder cooked in chicken broth;

100 g cooked chicken meat without skin;

1 tsp of vegetable oil;

1 tsp of fish, liver or tuna oil;

0.5 tsp KCl;

Multivitamin supplement (See Chandler, Pg. 529, left middle insert).

Chandler does not disclose the exact contents of the multivitamin supplement used in the prepared diet; however, at page 531 Chandler elaborates that malassimilation and increased fluid loss associated with diarrhea may result in depletion of water soluble vitamin B complex and vitamin C. Fat

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soluble vitamins A, D, E and K may also be depleted due to fat malabsorption from diarrhea. Thus, because each of these essential nutrients may be depleted as a result of diarrhea, it would have been *prima facie* obvious to one of ordinary skill in the art to select a multivitamin that contained each of vitamin B complex, and vitamins C (ascorbic acid), A, D, E and K for inclusion in the diet of Chandler. Vitamin C, at least, is an antioxidant.

Please note that both chicken and rice are sources of glutamine (See "Glutamine" The World's Healthiest Foods (chicken) & Hamada et al, Pg. 319, col. 2 (rice)). However, it was further known in the art that glutamine is the preferred fuel source for enterocytes, is essential for optimal gastrointestinal function during times of metabolic stress (such as during bouts of diarrhea or GI disease), and plays a role in immune function, stimulating both B and T lymphocyte function (See Hickman, Pg. 215, col. 1 & Chandler, Pg. 529, col. 2, and especially Pg. 533, col. 1). Thus, while glutamine is inherently provided in the diet of Chandler, supplementation of the diet with additional glutamine for the express purpose of strengthening the cells of the intestinal mucosa and enhancing immune response would have been *prima facie* obvious to one of ordinary skill in the art.

Chandler states the diet is suitable for treatment of gastrointestinal disorders in adult cats; however Chandler does not specify the gastrointestinal disorder can be inflammatory bowel disease.

Guilford teaches inflammatory bowel disease in cats and dogs can be treated through a combination of immunosuppressive and dietary management. The diet should be highly digestible, gluten-free, low in fat and lactose, hypoallergenic, not markedly hypertonic, and contain overages of potassium, water- and fat-soluble vitamins (See Guilford, Pg. 623, col. 2 "Diets for Inflammatory Bowel Disease", which references diet disclosed at Pg. 622-623 "Chronic 'Small Bowel' Diarrhoea").

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The diet of Chandler satisfies the guidelines of Guilford as a suitable diet for management of inflammatory bowel disease. Specifically, the rice cereal, made from rice, contains rice bran; rice bran is an insoluble, moderately fermentable fiber source (See Hickman, Pg. 212, Table 1). Rice is gluten-free and usually hypoallergenic. The chicken meat, without skin, serves as a low-fat protein source. The vegetable oil provides omega-6 fatty acids (See Hickman, Pg. 213, col. 2). The fish oil provides omega-3 fatty acids (See Hickman, Pg. 213, col. 2). The KCl clearly providing the dosage of potassium. Therefore it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to feed the diet suggested by Chandler to a cat suffering from IBD, optionally in combination with immunosuppressive therapy. One would have had a reasonable expectation that the diet of Chandler would be an effective diet for the treatment of IBD based on the suggestion of Guilford that IBD can be managed through a highly digestible diet that is gluten-free, low in fat and lactose, hypoallergenic, not markedly hypertonic, and contains overages of potassium and water and fat soluble vitamins.

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega fatty acids, antioxidants, including vitamin C (ascorbic acid), and glutamine, it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment potential of the diet. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus the holding of obviousness is supported by legal precedence. Applicants have not shown that the claimed concentrations of any of the ingredients produce critical or unexpected results, the only

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comparisons provided in the specification are based on the presence versus absence of any one claimed component, which does not support criticality of a claimed range. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/  
Primary Examiner, Art Unit 1651